CURALINE
The Future of Wound Care

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5. 510(k) Summary

510(k) SUMMARY

NOV 30 2012

Curaline Polyurethane Foam DRESSING

1. **Submitters Name**: Curaline, Inc., USA.

   Telephone: (262) 422 -7423

   Email: info@curaline.com

2. **Regulatory Contact Person at Curaline, Inc.**: Mr. Haitham Matloub

3. **Date that 510(K) Summary was Prepared**: September 28, 2012

4. **Name of the Medical Device**: Curaline Polyurethane Foam Dressing

5. **Legally Marketed Devices to which Substantial Equivalency is Claimed**

   - PolyMem Foam Wound Dressing (Ferris Mfg. Co., K880330, K900127 and K932913) **Principal Predicate**
   - Allevyn Foam Wound Dressing (Smith-Nephew, K963096 and K871166) **Reference Predicate**
   - Mepilex Foam Wound Dressing (Molnlycke Corp., K983184) **Reference Predicate**

6. **Description of the Device:**

   The Curaline Polyurethane Foam Dressing is composed of a hydrophilic polyurethane matrix backed with a semipermeable polyurethane film which limits oxygen and moisture vapor permeability and is a barrier to liquids. The dressing contains a cleanser (F68 surfactant), a moisturizer (glycerin), and an absorbing agent (superabsorbent polymer), all in the polyurethane matrix. Both F68 and glycerin are soluble in wound fluid or skin moisture. The superabsorbent polymer contained in the dressing draws and absorbs moisture from wound fluid.

7. **Intended Use of the Device:**

   Curaline Polyurethane Foam Dressings are intended for the management of partial and full thickness wounds; pressure ulcers (Stage I-IV); diabetic ulcers; acute and chronic venous stasis ulcers; arterial ulcers; skin grafts, donor and recipient sites; burns (1st and

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2nd degree); skin tears and avulsions; abrasions; tube, catheter, and IV sites; dermatologic disorders; under compression bandages and wraps; traumatic wounds; acute and chronic wounds; and minimal, moderate, and heavily exuding wounds.

Rx only; Federal law restricts this device to sale by or on the order of a physician or other licensed healthcare professional.

8. Technological Comparison between Subject and Predicate Devices:

Curaline Polyurethane Foam Dressings are sterile, conformable foam wound dressings and are made in various sizes and configurations to conform to the requirements of wound management protocol. The Curaline Polyurethane Foam Dressing is chemically and physically equivalent to the principal predicate and substantially equivalent to the reference predicate wound dressing devices.

9. Summary of Studies and Conclusions from Biocompatibility Tests:

Curaline Polyurethane Foam Dressings were evaluated through in-vitro and animal safety studies. All of these results are consistent in indicating that this product is safe for use in absorbing exudates and providing a moist environment for the wound site.

Safety tests and the conclusions drawn for the test articles:

- Cytotoxicity: Agar Diffusion Test – ISO: Product is non-cytotoxic and meets the requirements of the Agar Diffusion Test defined in ISO 10993-5 guidelines.
- Primary Skin Irritation Test – ISO Direct Contact: Product is considered a negligible irritant after a single topical 4 hour application to the skin of New Zealand White rabbits. No signs of Erythema or edema were noted at any observation period.
- Buehler Sensitization Test – ISO Direct Contact: The product is not considered to be a skin sensitizer; no reactions were observed in the negative control group.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Curaline, Incorporated
% Mr Haitham Matloub
President
10554 North Washington Port Road
Mequon, Wisconsin 53092

November 30, 2012

Re: K121361
Trade/Device Name: Curaline Polyurethane Foam Dressing
Regulation Name: Unclassified
Product Code: FRO
Dated: October 31, 2012
Received: November 06, 2012

Dear Mr. Matloub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CURALINE
The Future of Wound Care

4. Indications for Use Statement

Indications for Use

510(k) NUMBER (IF KNOWN): K121361

DEVICE NAME: Curaline Polyurethane Foam Dressing

INDICATIONS FOR USE:

Curaline Polyurethane Foam Dressing is indicated for use in the management of:

- **Partial and full thickness wounds**
- **Pressure ulcers (Stage I-IV)**
- **Diabetic ulcers**
- **Acute and chronic venous stasis ulcers**
- **Arterial ulcers**
- **Skin grafts; donor and recipient sites**
- **Burns (1st and 2nd degree)**
- **Skin tears and avulsions**
- **Abrasions**
- **Surgical wounds**
- **Tube, catheter, drain and I.V. sites**
- **Dermatologic disorders**
- **Under compression bandages/wraps**
- **Traumatic wounds**
- **Acute and Chronic wounds**
- **Minimal, moderate and heavily exuding wounds**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X_____ OR Over-the-Counter-Use ___

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ____K121361_____

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